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Medicines and Healthcare products Regulatory Agency

EVALUATION

MHRA 04103

Alaris Asena GW Volumetric pump

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Alaris Asena GW Volumetric pump

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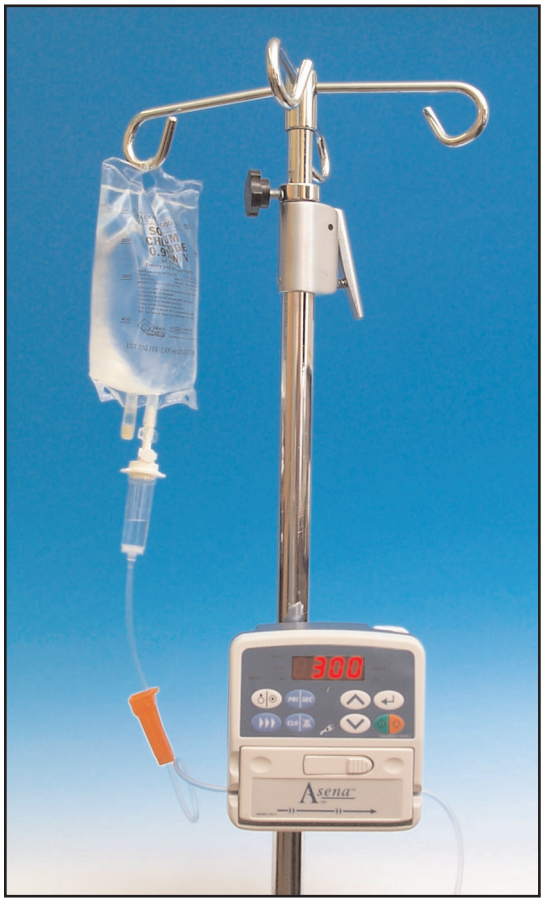
Summary

Brief description



The Alaris Asena GW LVP (Large Volume Pump) is an unusually compact volumetric pump, being both small and light. The pump can be integrated into a multi-pump infusion system including Asena syringe pumps, and other GW volumetric pumps. An Asena docking station is necessary to achieve this. The pump can also be mounted on Draeger bar or vertical pole.

The pump uses dedicated sets with or without anti-free-flow valve and has a simple user interface allowing setting of basic infusion parameters. Secondary infusions can be programmed, and bolusing enabled in the configuration. Alarms occur for usual causes including occlusion and air-in-line

Advantages

The pump is small and light.

The set is easy to load and the pump very easy to operate.

Additional features such as piggyback infusions can be added in the configuration.

The pump is compact, and can be integrated in the Asena docking station with Asena syringe pumps.

Disadvantages

No anti free-flow device in some of the administration sets. (MHRA recommends the use of anti free-flow sets for critical care).

When present in the set, the anti free-flow valve is of a kind which requires the use of the pump to prime the set. Also it prevents use of the set for gravity infusions.

Upstream occlusion alarm is fully functional only if the drop sensor is purchased. (Pump shown here without sensor.)

Faults during testing

Ruptured administration set: a piggyback set was caused to leak by pressure generated during the pump's routine startup check. This could recur, as the piggyback set has a one-way valve deliberately included to prevent back flow

towards the secondary container. The pump pumps backwards briefly during startup checks, in order to assess the integrity and correct positioning of the set. The problem is only relevant where a piggyback set is used with only one container attached. Sets other than the piggyback set are also unaffected, as the absence of the one-way valve above the pump allows some backwards movement of fluid.

Main Features

Power Supply 100-120 V AC, 50/60 Hz, 10VA (nominal; 220-240 V AC, 50/60 Hz, 10 VA (nominal); rechargeable NiMH battery

Administration set The pump was tested with the 273-004, with 15µm filter in drip chamber, no y-site, back check valve; there are also burette, secondary, opaque, anti-syphon valve sets.

Flow rate range 1 to 999 ml/h in standard mode, 1.0 ml/h to 99.9 ml/h in micro mode

Pump mechanism peristaltic

Occlusion detection Lo (250 mmHg), Nor(mal) (350 mmHg), Hi (500 mmHg)

Air detection Configurable single bubble of 50, 100, 250, 500 µl, cumulative > 500 µl over 15 minutes

Alarms and alerts **Alarms:** Air in line, upstream occlusion, internal battery depleted, door open, system fault, flow error (if drop sensor in use), flow sensor connection error, downstream occlusion, misloaded or otherwise incorrect administration set. **Warnings:** bolus being administered, end of infusion, pump is priming, low battery, pump on hold, pump unattended, automatic set check in progress.

Price (ex VAT)	£2,680
Manufacturer	Alaris Medical U.K. Limited, The Crescent, Jays Close, Basingstoke, United Kingdom RG22 4BS Tel: 01256 388200 Fax: 01256 330860
CE Marking	Yes
Notified Body	0086, BSI Product Services, Hemel Hempstead, UK
Certified to Standard?	IEC 60601-1; IEC 60601-2-24

Photographs

Figure 1. Front of pump, door closed

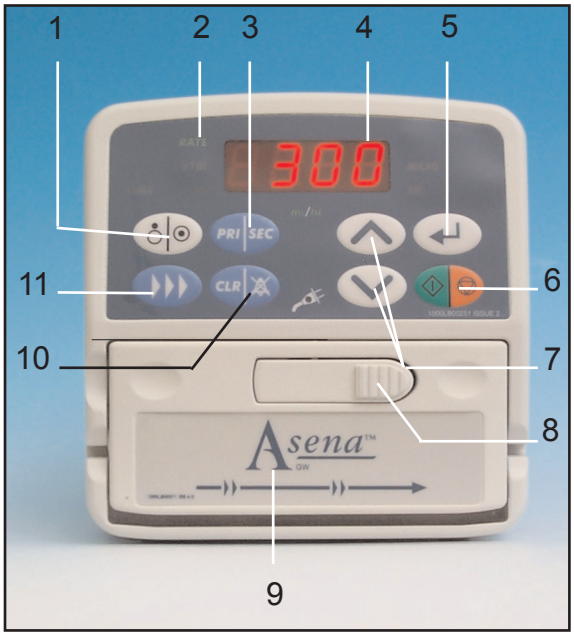
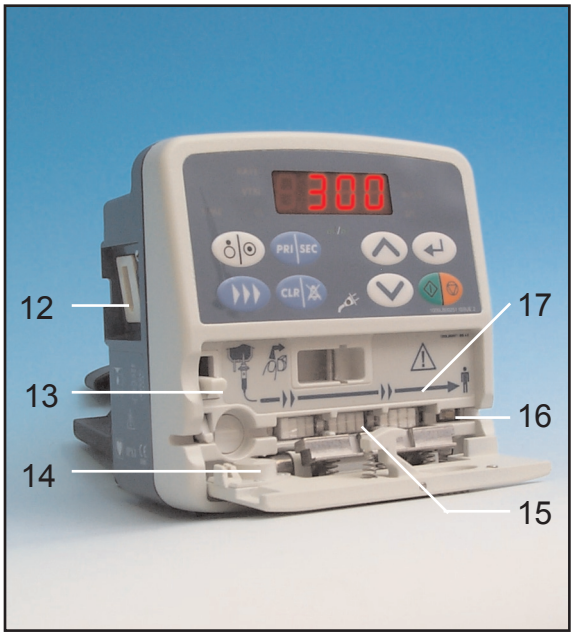


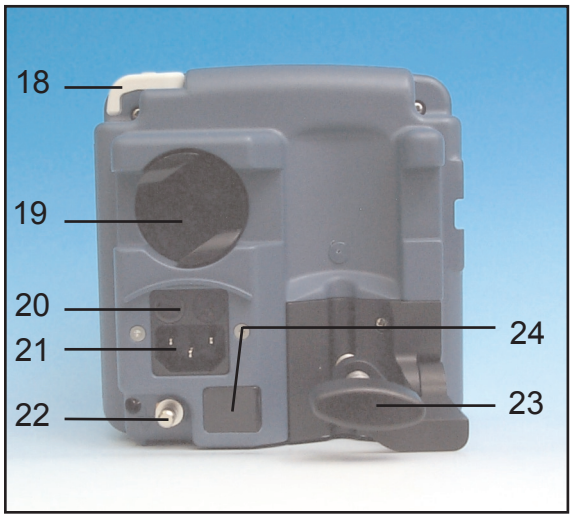
Figure 2. Front of pump, door open



Key to Figures 1, 2 and 3

1. On/Off
2. Illuminated text messages- volume or rate
3. Primary/Secondary
4. Main display
5. Enter key
6. Run/Hold
7. Chevrons - increase and decrease
8. Door latch
9. Door in closed position showing flow direction arrow
10. Clear/Silence alarm
11. Prime/Bolus button
12. RS232/Nurse call and flow sensor sockets
13. Flow stop mechanism
14. Air sensor
15. Tubing Guide
16. Pressure sensor
17. Flow direction arrow
18. Release lever for horizontal bar clamp
19. Horizontal rectangular bar clamp - can also fix pump to docking station
20. AC fuses
21. AC power connector
22. Potential Equalisation (PE) connector
23. Extended pole clamp for vertical pole (can be folded back into recess)
24. Infra Red communications port (IrDA)

Figure 3. Back of pump



Evaluator assessment of ergonomics

Alaris Asena GW

The Alaris Asena GW LVP (Large Volume Pump) is an unusually compact volumetric pump, being both small and light. The pump can be integrated into a multi-pump infusion system including Asena syringe pumps, and other GW volumetric pumps. An Asena docking station is necessary to achieve this. This docking station was not assessed during this evaluation.

The pump can be mounted on either a vertical drip stand or a Draeger (horizontal) rail, using one or other of the two clamps. The presence of two clamps at 90 degrees to each other makes possible the clamping of the pump incorrectly with the flow channel positioned vertically rather than horizontally. This is a use error which is very unlikely to occur and is mentioned here only because the Directions for Use (DFU) warn against using the pump in this orientation. It is hard to imagine an authorised user would ever make this mistake.

The pump can operate in either rate/volume mode or volume over time mode - only one of these modes is enabled in the configuration at any time. By default, this is usually rate/volume mode. In addition, piggyback programming, user administered bolus, and Keep Vein Open (KVO) modes are available. Instructions for configuring these additional modes are included in the technical manual.

Rate can normally be set in the range 1-999 ml/h and rate is incremented in steps of 1 ml/h or larger, dependant on how long the increment key has been pressed. It can take some practice to avoid overshoot when setting the rate. This lengthens the time taken to set an intermediate rate starting from the default in the early stages of use, but the problem would probably disappear with time and practice.

Rate can be incremented in steps of 0.1 ml/h if the optional micro mode is enabled in the configuration. In this mode rate is limited to values between 1 and 99.9 ml/h. Precision but not accuracy is improved in this mode.

Occlusion alarm pressure can be set by the user at one of three levels. Air in line detection limits are only settable using the technical manual, as a coded key combination is required.

A large range of dedicated administration sets can be purchased for use with this pump, exclusively from Alaris. The set has no particular key or locating feature which ties its design specifically to use in this pump or vice versa. The pump assesses during its startup routine whether a set of the correct specification has been loaded. There will be a margin for error on this measurement so that the use of incorrect or third party sets is theoretically possible. MHRA strongly recommends that correct sets, as recommended by the manufacturer, are used.

It is also strongly recommended by MHRA that pumps are used with sets having anti free-flow valve. It is unfortunate that this is an optional feature for this pump/set. The greatest cause of patient harm from adverse incidents involving volumetric infusion pumps is due to free-flow. A set with anti free-flow valve can be purchased, however (273-001). The type of anti free-flow valve offered is opened only by increased delivery pressure, so that priming of the set outside the pump is not possible. Anti free-flow valves which are automatically activated by the pump but can be opened by the user for priming, leave the user with more options, whilst still protecting the patient.

Technical performance of the pump is detailed in the technical assessment section of this report. User views are summarised in the user assessment section.

User Interface

Front panel indicators

The main display comprises an assembly of four bright-red seven-segment LEDs. This measures 50 x 16 mm and indicates numeric parameters such as rate and (when requested) Volume to be Infused (VTBI) or volume infused. A separate illuminated text to the left of the main display indicates the parameter currently being displayed and/or changed. The main display is easily visible from a wide field of view, and characters are not excessively recessed.

The main display is bright and easily legible, whereas the illuminated text indicators are somewhat dim, and not easily seen, especially in bright ambient lighting conditions. The texts ‘rate’, ‘volume’ and ‘time’ appear appropriately to the left of the main display and the illuminated text ‘ml/hr’ appears beneath the main display. Green LEDs illuminate the texts ‘ml’, ‘hr’ or the whole text (‘ml/hr’). The difference between these visual indicators beneath the display is too subtle to be useful. Since rate is displayed by default, however, and display of any other parameter involves user action by pressing the enter key, there is unlikely to be any significant confusion caused.

Front panel controls

See photographs for controls. There are relatively few, as the pump has a basic but straightforward set of functions. The keyboard is well laid out, there are separate On/Off and Start/Stop buttons. Where keys are multi functional the dual functions are related, and not difficult to predict. In general the user interface is simple and intuitive. The pump supplied for evaluation had the default configuration, with secondary infusions, boluses, and micro mode disabled (see infusion modes) which renders the PRI/SEC key redundant but this should not cause any problems.

Use of the keys is accompanied by a beep, whether or not the key is in a functional state, for instance attempts to ‘increment’ the volume infused using the increment key - clearly a nonsensical procedure - generates beeps for key press, but no resulting change in the volume infused display. This is not the case in the sister pumps, the Asena syringe pumps, where non-functional keys provide no beep when pressed. There is therefore some small potential for confusion here when the two types of pump are used together, such as in the docking station.

All keys are of a good size, and easy to operate. Conventional symbols are used for On/Off and Enter, and the function of other keys is also clear. The only potentially confusing key press is the use of the Start/Stop key to put the pump on Hold during an alarm situation (see above).

Set Loading

Loading the set is very easy, once the user has understood that the flow stop mechanism within the pump needs to be opened first. The set is threaded through the flow channel from left to right (in the conventional direction). Flow direction arrows are present both on the door and inside the door to assist in placing the set correctly. It is possible to load the set in the wrong direction. If this is achieved, despite the arrows, then flow occurs briefly in the wrong direction and a “bad set’ alarm is given. This alarm occurs more rapidly if the pump is being set up for the first time since switch off. Subsequent attempts to run the pump with set misplaced, result in slightly longer alarm time. In either case, alarm occurs within a minute.

Infusion options

Rate can be set either in ml/h with obligatory Volume to be Infused (VTBI), or as a volume over time. The two modes are alternatives, and are enabled within the configuration menu, which appropriately is not available to the bedside user. In addition primary/secondary infusion can be programmed, if enabled in the configuration. The display shows ‘SEC’ whilst the secondary infusion runs through. It then reverts to normal display and emits a beep when the primary rate initiates.

Boluses, if enabled in the configuration, can be administered using the dual function prime/bolus button. This requires two key presses; the first key press displays the message ‘bol’ and the second administers a bolus, accompanied by an incrementing display of the volume of the bolus. The volume of the bolus is added to the volume infused and subtracted from the volume to be infused. It is not possible to exceed the set VTBI using the bolus button.

Rate can also be titrated without stopping the pump. This requires two key presses; the first to increment or decrement the displayed rate and the second to confirm and implement the change. The double key press is a safeguard against tampering.

Setting the rate and initiating the infusion

Rate and other parameters such as time, volume to be infused are set using the increment keys.

Micro mode, if configured on, allows setting of rate in increments of 0.1 ml/h. The minimum rate remains 1 ml/h in both micro and standard modes with a maximum of 99.9 ml/h in micro mode, and 999 ml/h in standard mode. Normally rate increments in 1ml/h steps, increasing to 10 ml/h steps depending on how long the increment key is pressed. The rate decrease chevron has no effect from the default display of 0 ml/h, so that a rate of 999 ml/h cannot be inadvertently set by decrement from low rates. This is a safety feature to prevent inadvertent setting of maximum rate when a low rate is intended.

When setting the rate, the increasingly rapid rollover rate can cause overshoot. For instance overshoot by 100 ml/h returns the user to the decrement key operating in steps of 1 ml/h, increasing to 10 ml/h with sustained pressure. Stopping pressing the key at the right time to prevent overshoot and allow quickest homing in on the desired rate comes with practice.

Starting the infusion initiates a self-check routine for the pump. This includes a period of pumping first backward and then forward, to check the integrity of the set. The backward pumping caused difficulties for the administration set with one-way valve above the pump (see Faults during testing). A very small bolus is also delivered during this period, and flow backwards in the cannula occurs but this is too small to show up on the flow graphs when viewed over the first 30 seconds and is unlikely therefore to be clinically significant.

Security features

The On/Off key has a 3 second delay requiring the user to continue pressing for this period before it is effective. This serves to prevent accidental turning off of the pump.

Titration of rate and administration of boluses (if enabled) require two key presses, once again to prevent tampering.

The panel can be locked by the user by pressing the two chevron keys simultaneously. The lock is released using the same two keys.

The pump configuration is largely protected from inadvertent changes by requiring a double key press for access. There is no numeric configuration code; the double key press for access to the configuration menu is described in the technical manual, which complies with MHRA recommendation that configuration changes should be made centrally by technical staff, rather than by the bedside.

Configuration changes available to the user are limited to occlusion pressure alarm level, alarm volume, enabling micro mode, or changing to time/volume mode from rate/time mode. The Enter key is pressed and held to access these changes. It is possible to disable these user accessible configuration changes. See below (Configurable options) for other configurable features.

Alarms and alerts

The alarm tone is distinctive and volume can be adjusted. Visual messages are displayed on the LED screen, and are clear and unambiguous. Messages prompting the user to remedial action are not provided.

Alarm and alert both provide visual and audible signal to the user.

Alarm is given for upstream occlusion, internal battery depleted, door open, system fault, flow error, flow sensor connection error, downstream occlusion and incorrect or badly loaded administration set.

Alerts are given for bolus being delivered, end of infusion, pump priming, low battery, pump on hold, pump unattended for more than 2 minutes, and ‘test’ - indicating an automatic test sequence is being executed.

When the pump detects any of the alarm conditions the infusion is stopped and the audible and visual alarms are activated. The audible alarm is accompanied by display of an abbreviated text message on the seven segment display, for instance an occlusion is indicated by the message ‘HI PrES’. This message is only viewable from the front of the pump. When viewed from other angles, the only indication of alarm is the audible tone.

Alerts indicate non-critical warnings such as volume infused complete with KVO operating. Once again an audible beep is given, but the user can silence the tone, and pumping continues. Alerts (referred to as warnings by Alaris) are listed on page 2. An explanatory list of alarm texts and warnings is given on the side of the pump, a quick reference card can also be attached to the pump. Advice on the appropriate remedial action to take during alarm is given in the Directions for Use (DFU), but does not include mention of the rather counter-intuitive necessity to press Run/Hold twice in order to restart the infusion. (The first press of this key cancels the alarm message display, and places the pump on HOLD, despite the fact that pumping has already stopped. A second press is required to resume pumping.)

The occlusion detection system detects the pressure within the administration set just downstream of the pumping mechanism. The alarm pressure can be set at three levels - Hi 500 mmHg, NOR(mal) - 350 mmHg and Lo - 250 mmHg. The user can change alarm pressure settings with the help of a series of key presses described in the DFU. The default limit is Hi. The pump has a ‘backoff’ function programmed to reduce occlusion bolus on occurrence of occlusion alarm; the bolus

potentially delivered to the patient is small at around 0.02 ml for all flow rates with occlusion alarm level set at Lo.

Air-in-line alarm is given for both single bubbles greater than the limit (configurable, but not by the user, between 50 and 500 µl), and a cumulative volume of smaller bubbles passing the detector, amounting to more than 500 µl in 15 minutes. Neither air detection system can be disabled, and the two systems run in parallel.

The drop sensor, if used, provides reliable alarm for upstream occlusion. A rudimentary upstream occlusion alarm operates in its absence, which depends on the air detector registering the reduction in the diameter of the set as ‘air’.

Configurable options

The default configuration of the pump is provided in the technical service manual along with instructions on how to change each parameter. The restriction of access to technical personnel of configurability is appropriate. MHRA strongly recommends that configuration changes are made centrally by technical staff, not at the bedside, and that all pumps in one clinical area are configured identically. This removes the possibility of user confusion and error caused by unexpected key functions.

In addition to the features already mentioned, the following parameters and facilities can be altered in the configuration menu.

- volume/time or rate/VTBI
- maximum priming volume
- clear infusion parameters on power on
- maximum VTBI in Micro mode
- bolus rate
- maximum bolus volume.

The pump has a teach/learn facility which allows downloading of configuration from a ‘master’ pump to others. This feature was not evaluated but is potentially labour saving to technical staff, and promotes uniform configuration of all pumps which will contribute towards minimising user error.

Manuals

A comprehensive 27 page A4 manual, referred to as the Directions for Use, is provided with each pump. This manual is very well laid out with a contents list on the front cover. There is no index, but the manual was nonetheless easy to refer to, the material being arranged in logical and labelled order. Diagrams are provided, showing all parts of the pump and administration sets. An illustrated list of all the controls is also given, which is excellent. Clear advice (excepting use of Hold key) is given on how to proceed in the event of alarm. The technical performance of the

pump is presented at the rear of the manual, in unusually comprehensive and accurate format e.g conditions of testing are given.

The technical manual is similarly accessible and good with clear exploded diagrams showing disassembly and reassembly procedures. The list of default configurations and instructions on how to change these, are also provided in the technical manuals. Once again there is a contents list with page numbers, but no index.

There are no brief instructions provided on the body of the pump. A quick reference guide which includes instructions can be attached to the pump but this was not provided for evaluation. A list of alarm causes is given on the side of the pump.

History logging

The pump stores approximately six months' worth of events. The technical manual states that 'software is currently under development to enable users to download Event Logs' and advises contacting a local Alaris representative. Alaris state that this software is now available. It was not provided for evaluation.

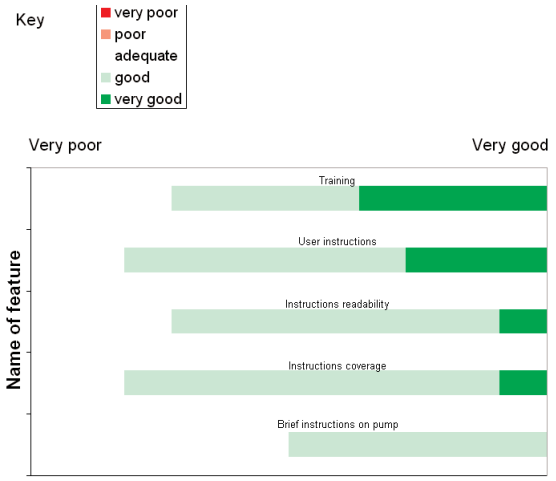
Cost

The list price for the pump is £2680 (ex VAT). The set used for evaluation (Administration set: 273-004, 15 µm filter in drip chamber, no y-site, with back check valve) is £251.70 per 100.

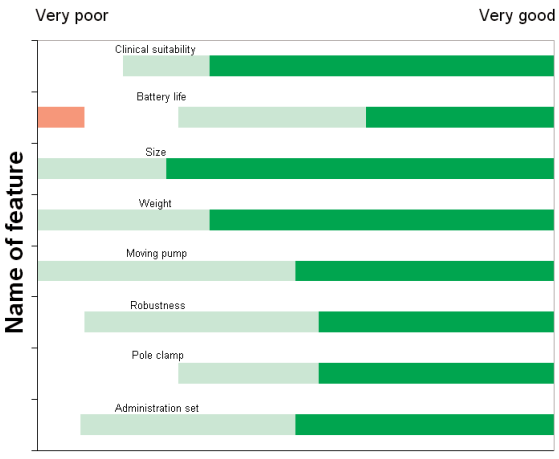
User assessment

To provide a user assessment for the Alaris Asena GW LVP pump two Trusts were contacted. Both Trusts have a significant number of pumps in use in an Intensive Care Unit. Three senior nursing staff responded from one Trust and 9 nursing staff with a range of responsibilities from the other. The pump is used on a daily basis in both units. Appendix 1 gives a sample of the questionnaire used. The results of the questionnaires have been collated and the following sections represent a summary of findings from both centres. Users' views have not been edited, but appear as stated by the individual users. In some cases users' views were contradictory, particularly between the two centres. This emphasises the need for on-site evaluation by users prior to purchase. The context in which the device is used is significant to whether the device is found suitable.

Users were also asked to grade each feature on a scale of 1 to 5 where 5 was very good and 1 was very poor. These results are presented graphically on the left with user comments given on the right.



Full width of graphs = 100% of respondents



Training and user instructions

- User instructions not used as machine instruction given by a previously trained colleague
- Coverage of instructions was clear and concise.

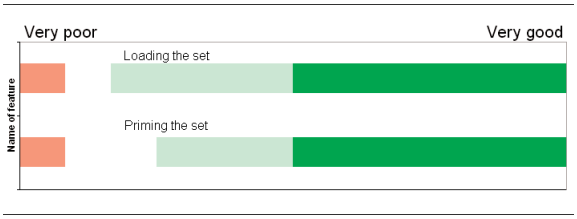
BIME Note: Product training was generally provided by the manufacturer. A few users had been trained by a previously trained colleague. Alaris state that manufacturer training is available to all users, but is not always taken up.

Appropriateness of device and set

- Unable to comment on robustness, as the pump has never been dropped.
- The device was suitable for our application because compact.
- Easy to handle /hold whilst clamping to stand
- Weight is satisfactory to hold with one hand.
- Device not used on battery power
- (Batteries) appear to run down quickly but are probably not kept plugged in properly

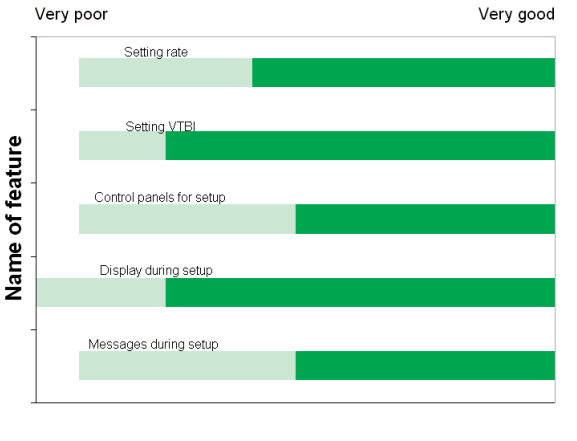
- Much prefer gravity fed set for priming, do not understand need for two different sets
- Prefer gravity fed set
- Have changed to anti-syphon set, did not initially know this was available.

Loading the set

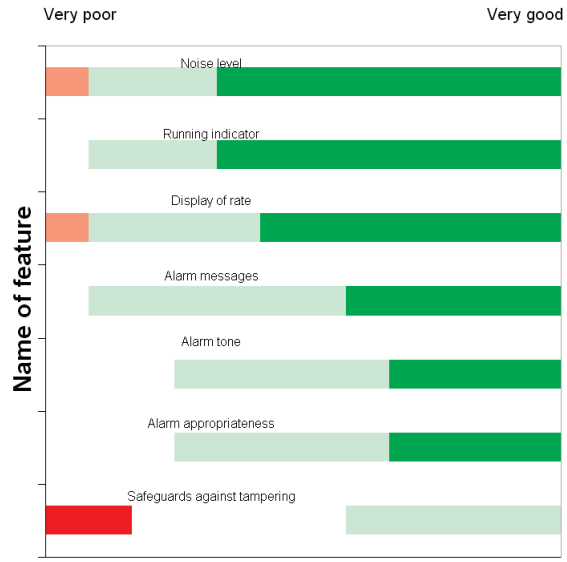


- Whilst using the device to infuse a sedative medication the line was initially fitted correctly and infused the medication appropriately. Shortly after setting up the device the situation and environment had to be changed slightly, the device had to be stopped and the line disconnected for a short time. When refitting the line, the line became trapped in the hinge. The device continued to infuse at a quicker rate than set and did not alarm, it was noted by staff only when the patient's blood pressure decreased and staff noted the rapid use of the medication. This only happened on the one occasion.
- Loading of the set is easy.
- The set-loading procedure is slow.
- The priming procedure is easy.
- The priming procedure is slow.
- The priming procedure is time-consuming

Setting the parameters



- Rate and VTBI are easy to set, and clear to see.
- The visual displays are clear.
- The messages provided by the pump are easy to understand
- It can take a little while to set the rate or VTBI. Pressing the arrows causes rate to suddenly go up very quickly, then down too far etc.

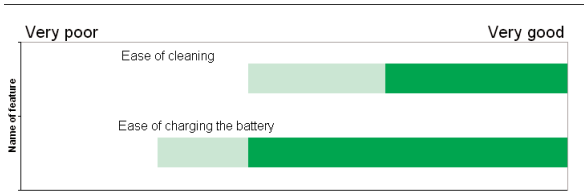


Monitoring the Infusion

- Do not know of any safeguards against tampering.
- What safeguards against tampering?!
- There is no lock.

BIME Note: Users were evidently not aware of some of the security features such as the panel lock.

- The pump is quiet in operation
- The alarm messages give clear indications of the cause of any problem.
- The display of rate VTBI is inadequate. Prefer to be able to see figures rather than having to press button/s.
- The noise level whilst running was too noisy
- The alarm tone was noisy
- Alarm tone good, it can be adjusted.



Infusion complete

No comments on this section by users.

General comments

- On starting the device the alarm is loud
- The switch-on alarm is very loud. Could be a little quieter or shorter. Not good within night time setting, however the alert alarms are adequate.
- The pump would be improved by easier volume to be infused settings
- There are no features present which are unsuitable for our application.
- Display of drug or infusion as the syringe drivers do would be useful.
- We don't really use the clock feature that enables you to set the time of the infusion.
- Bolus very slow
- Filling giving set very slow

Summary comments

- This is the best IV or syringe pump I have had the opportunity to use.
- In an emergency it appears to be lengthy when giving a bolus.
- Slow to prime and give bolus doses, this is poor in an ITU situation where you need to give extra sedation quickly.

Summary comments (continued)

- I have found the pumps alarming “infusion complete” when there is sometimes up to 150ml left to infuse. This is NOT a user fault; it tells me that the pump is not recording accurately. I have noticed this more over the last few months. It makes me unhappy to use these pumps.
- Bolus often difficult to give.
- The pump is very easy to use. Very precise when in micro mode. It takes up only a small amount of space and is very lightweight.
- On occasions large volumes still left in infusion bag despite volumes of 500 shown to have been delivered.
- On two occasions very experienced nurses found their infusion (which had been checked and set) ran through very quickly and it was felt it was the pump, however no problem was found with the pumps (returned to EBME etc.). We now have the anti-syphon giving sets that we were not aware of until the above incidents. Generally, we felt dissatisfied that both incidents were unexplained! However overall we find the Asena GW a good, user-friendly general use pump.
- There are no features that are present on the pump which are unsuitable for our application.

Long term accuracy

Table 1. Long term accuracy results for Asena GW

Flow rates tested	Greatest over delivery	Greatest under delivery	Accuracy at minimum flow rate
1 to 999 ml/h	+5.3% (at 1 ml/h)	- 4.9% (at 500 ml/h)	+5.3 % (at 1 ml/h)

The Asena GW was tested over the full range of flow rates from 1 to 999 ml/h. The default administration set, provided with the pump for evaluation, is 273-004, a standard set with 15 µm filter in the drip chamber, no y-site, and a back check valve but no anti free-flow valve.

Results of the long term accuracy tests are presented above. The worst cases of over and under-delivery errors measured over any hour period during the recommended period of use of the set (24 hours) were +5.3% and -4.9%. In general, results were centred around zero error fairly closely. This level of accuracy is appropriate for general ward use. Figures 5 and 6 show flow at 1 ml/h, plotted over 24 and 2 hours.

It was also noted during testing that the back-check valve closely resembled an anti-syphon valve. If the set is removed from the pump whilst attached to the patient, under the mistaken impression that free-flow is prevented by the back check valve, it is possible for free-flow to occur. The use of the set with anti-syphon valve would be strongly recommended to prevent accidental free-flow.

Very low flow rates (less than 1 ml/h) should be used with caution. Performance at such low flow rates is erratic for any pump, and is more likely to be inaccurate than at higher flow rates. Stringent efforts should be made to adjust therapy so that the lowest flow rate used with any infusion is appropriate to the type of pump in use. Volumetric pumps generally provide more discontinuous flow patterns than syringe pumps. Where possible, flow rates in excess of 5 ml/h should be used if drugs with

Figure 5. Long term accuracy at 1 ml/h over 24 hours

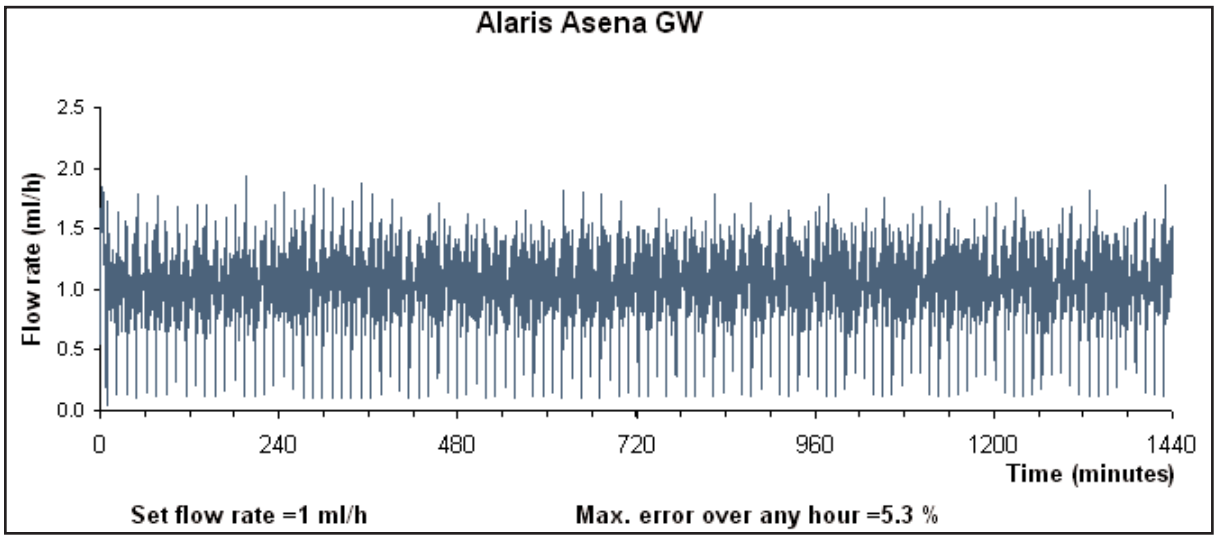
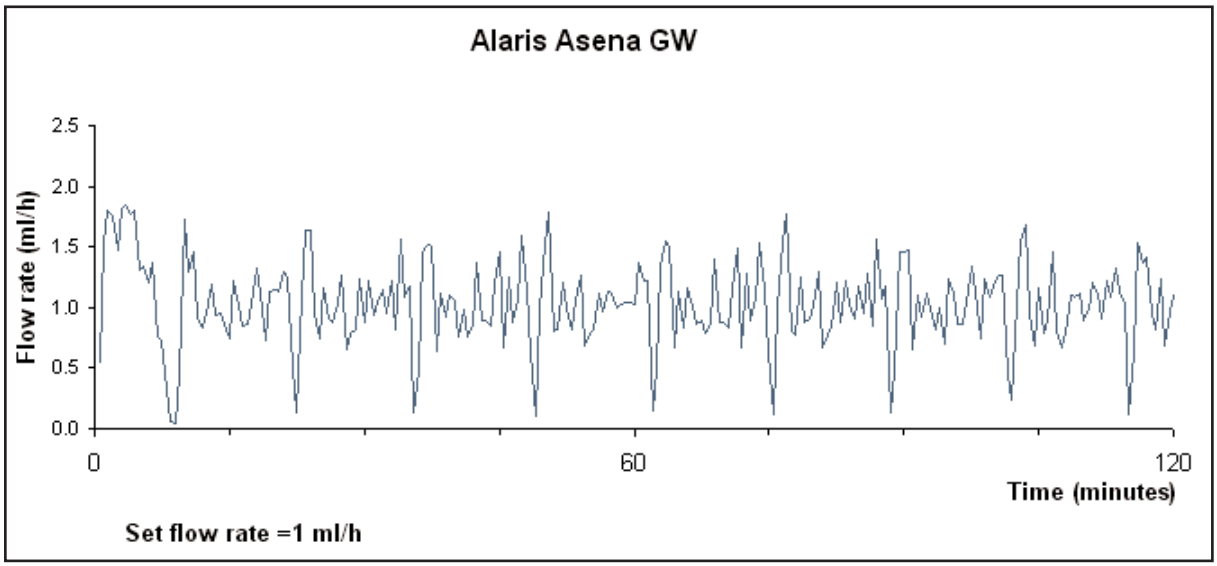


Figure 6. Long term accuracy at 1 ml/h over 2 hours



short half lives are in use with a volumetric pump. This can sometimes be achieved by dilution, but appropriate clinical note should be taken of dilution instructions and the risks associated with the dilution procedure e.g. contamination or miscalculation.

Short term accuracy and startup time

Table 2. Short term accuracy results for Asena GW

Constancy index	Startup time
7.5 minutes (at 1 ml/h)	2.5 minutes

Short-term accuracy of infusion pumps is expressed in terms of constancy index. The constancy index can be translated as the shortest half-life of a drug that would be recommended for administration at this flow rate with this pump. Constancy index is measured at 1 ml/h and indicates the minimum period of time over which the flow rate remains within 10% of the mean flow rate.

The constancy index for the Alaris Asena GW is 7.5 minutes which is reasonable for a volumetric pump. Short half life drugs are unlikely to be candidates for administration on general wards. The above result indicates that drugs with half-life shorter than 7.5 minutes would not be recommended to be delivered using this pump at low flow rates around 1 ml/h. The startup performance (2.5 minutes) is short compared with most syringe pumps. Startup time is a measure of the time at the start of an infusion that is taken for flow rate to stabilise at the set rate.

Volume to be infused

Table 3. Volume to be infused results for Asena GW

Target	Actual
1 ml in 60 minutes	+7.5% volume error, over 59m 59s
25 ml in 60 minutes	+0.5% volume error, over 59m 59s

These results indicate typical levels of accuracy for a volumetric pump. Delivery of small volumes over a short period (e.g. 1 ml/h over 1 hour) is unlikely to be achieved with high accuracy, and is not an appropriate application for a volumetric pump.

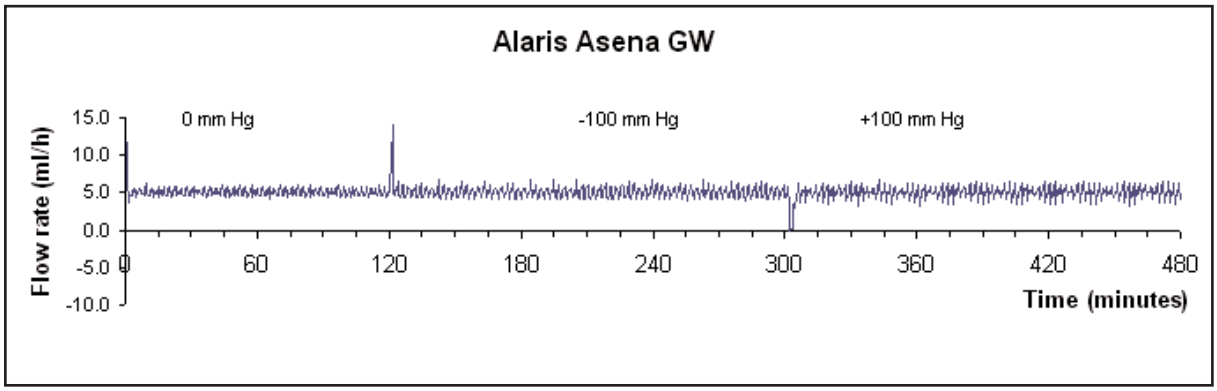
Back pressure

Table 4. Back pressure results for Asena GW

Back pressure	Accuracy	Bolus (when back pressure changes)	Resumption time
0 mmHg	+1.7 %	Not applicable	
-100 mmHg	+1.8 %	0.11 ml	
+100 mmHg	+1.9 %	-0.14 ml	2 minutes

The pump was set up to deliver at 1 ml/h for 8 hours. The pump was positioned so as to align the pumping with the level of the cannula outlet. After two hours, the pump was raised by 136 cm to simulate a drop in back pressure of 100 mmHg below ambient. After a further three hours the pump was lowered by 272 cm, to increase the back pressure to 100 mmHg above ambient. The pump was not stopped during repositioning. Figure 7 shows the flow rate of the pump during this 8 hour test.

Figure 7. Back pressure test at 1 ml/h over 8 hours



The flow graph (Figure 7) illustrates the potential hazard to the patient of moving a pump vertically in relation to the venous access site whilst the pump is delivering. When the pump is raised, a bolus is delivered to the patient, resulting in a temporary overdose. When the pump is lowered, flow from the pump temporarily ceases due to the backwards flow of fluid in the administration set. The back-check valve prevents fluid from being sucked back through the cannula however - (this fluid would be blood in the case of venous access). Flow does not resume for 2 minutes, after this change in height has been made.

The performance of this pump is similar to other volumetric pumps. It is important to know of this phenomenon, in order to minimise patient/pump relative movement during infusion.

Battery test

The Asena GW has a Nickel Metal Hydride (NiMH) battery with estimated capacity to drive the pump at 125 ml/h for more than 2 hours. The life of the battery was tested, from a point of maximum charge, and it was found the pump operated accurately at 125 ml/h for 525 minutes (8 hours 45 minutes) which substantially exceeds the manufacturer's claims. A 'Lo bAt' alarm message and intermittent audible beep were given approximately 30 minutes prior to shutdown. This alarm could not be silenced but occurs only once every 4 minutes or so. Final continuous audible alarm was given, with 'bAt' message displayed, on battery exhaustion and the pump shut down safely. The pump resumed accurate operation, and was able to recall previously set parameters on reconnection of the mains.

The manufacturer claims the pump achieves 95% charge in under 24 hours reconnection to the mains. This claim was not tested.

Container height test

The directions for use state that the fluid container should not be placed more than a metre above the patient's heart, however there is no locating key on the pump or set to prevent this from happening.

The pump was set to run at 125 ml/h with the bag normally positioned (drip chamber approximately 30 cm above the pump). Flow during this period showed a +2.7% error over an hour of established flow. The bag was then raised (drip chamber 85 cm above pump) and flow error was not significantly changed being +2.6% error over one hour. The bag was then lowered so as to be 50 cm below the drive mechanism of the pump, in order to simulate the bag being left on the bed, or some other such adverse, non-recommended set up. The flow rate was reduced slightly (flow error of -1.4%). All results remain well within the manufacturers claims, and are acceptable.

In general, however, it is not good practice to hang a container lower than the pumping mechanism of a volumetric pump.

Occlusion testing

Patient side occlusion

Table 5. Patient side occlusion results at 1 ml/h for Asena GW

Time to alarm	Post-occlusion bolus
14 minutes 49 seconds at 1 ml/h	0.03 ml at 1 ml/h

The pump was tested to establish the speed of response to occlusion and the volume of bolus on release of occlusion. The occlusion alarm pressure was set to the minimum level, LO which is roughly equivalent to 250 mmHg. Figures 8 and 9 demonstrate the change in time to alarm and post-occlusion bolus volume with flow rate.

Alarm time at 1 ml/h is relatively long for a volumetric pump at 14 minutes 49 seconds, although the post-occlusion bolus potentially delivered to the patient on release of the occlusion is small (0.03 ml). The pump mechanism backs off after occlusion alarm in order to minimise this bolus. The back-check valve effectively prevents suck back during this period, so that no negative boluses were observed during testing.

Fluid side occlusion

Fluid side occlusion is most efficiently detected if the flow sensor is in use, however this is an optional accessory and the pump was tested as supplied, in the default configuration and without accessories.

Fluid side occlusion can still be detected without the optional flow sensor, although not as reliably. Provided the occlusion was complete, our tests showed that an occlusion above the pump was reliably detected at maximum flow rate and 1 ml/h. Detection of upstream occlusion at 1 ml/h took 1 hour 8 minutes, so should not be relied upon where immediate alert is essential. The alarm given is AIR/OCCL. Pumping stops when the alarm is given.

It was noticed, however, that partial upstream occlusions (e.g. a not very tight roller clamp), could successfully prevent gravity flow when the set was outside the pump, but could allow flow when pumping started. The result was a gross underdelivery, without upstream occlusion alarm. The flow sensor should pick up this level of gross under-delivery, and it is therefore advisable to use it.

Figure 8. Time to alarm on occlusion

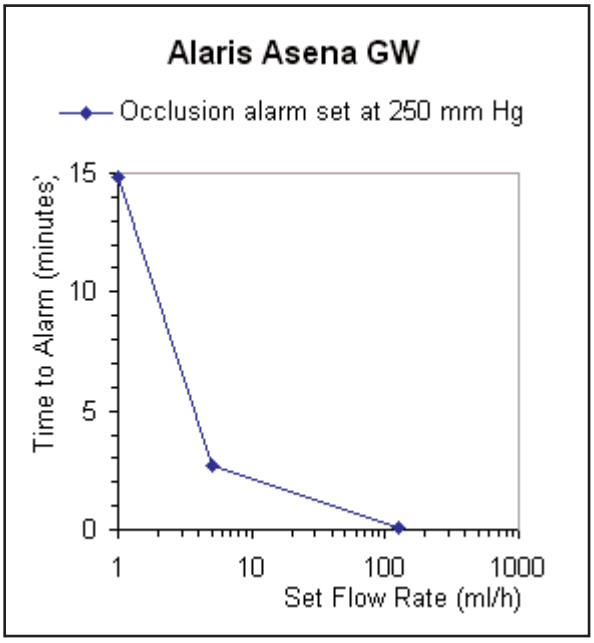
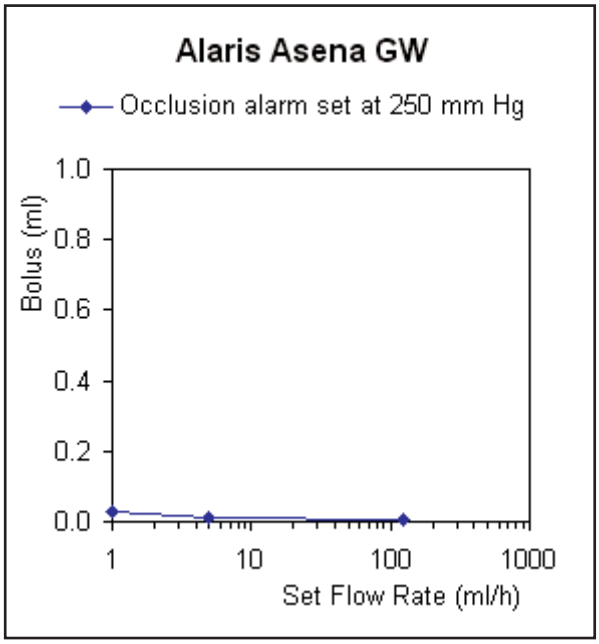


Figure 9. Bolus released after occlusion



Air-in-line testing

The Alaris Asena GW air-in-line detection system provides both single bubble detection (configurable) and cumulative air detection (not configurable). The air-in-line alarm is activated if a single air bubble of the pre-set volume is detected or if the cumulated volume of smaller bubbles over a 15 minute period reaches 0.05 ml. The minimum setting for detection of single air bubbles for the Asena GW is 50 µl and this configuration was used for testing. A single air bubble of 50 µl was introduced into the administration set upstream of the pump and the pump was set running at 125 ml/h - a typical rate for a volumetric pump. The pump reliably detected the 50 µl air bubble, triggering the alarm and ceasing delivery.

The sensitivity of the single bubble alarm can be set to 50 µl, 100 µl, 250 µl or 500 µl, the default configuration being 100 µl. It is not a bedside-user configurable parameter, as it requires information contained within the technical manual for the pump.

The cumulative air alarm was not tested specifically. It runs in parallel with the single bubble detection system, (neither can be disabled). Bubbles detected are of unspecified size, but the implication of the technical manual is that all bubbles including those smaller than the individual bubble alarm limit are summed for the cumulative alarm.

Faults during testing

Figure 10. Drop forming outside Y-site

During air in line testing it was noted that the injected bubble was sequentially compressed and then expanded by the action of the pump during start up checks. It was also noted that a leak resulted at the junction with the upper Y-site (see Figure 10). The explanation for this lies with the back-check valve that is present above the pump in the piggyback set. This valve intentionally prevents backwards flow. The pump's initial startup routine checks the integrity of the set by pumping first backwards and then forwards. Unfortunately, the presence of the back-check valve causes the pressure upstream of the pump to exceed the bursting pressure for the Y-site, with the result that fluid squeezes out. This is only the case where the piggyback set is being used without an additional container attached at the Y-site - a scenario which is possible prior to setup of the often smaller (second) infusion bag. This additional container is frequently added to the main line after the start of an infusion, on the order of a physician, and is referred to as the piggyback container.

Manufacturer's Data

Product Data	
Manufacturer and Supplier:	Alaris Medical U.K. Limited The Crescent, Jays Close, Basingstoke, United Kingdom RG22 4BS Tel: 01256 388200 Fax: 01256 330860 www.alarismed.com UK-Customer-Service@alarismed.com
CE Marking on Product?	Yes (MD Directive)
Country of origin/manufacture	UK
Price (ex VAT)	£2,680 Administration set: 273-004, 15 µm filter in drip chamber, no y-site, back check valve cost £251.70 for Qty 100
Size (H x W x D)	140 mm(H) x 137 mm(W) x 105 mm(D)
Weight	approx. 1.5 Kg
Power supply	220-240 VAC, 50/60 Hz, 10 VA (nominal)
Battery operation	Rechargeable NiMH
• battery capacity	> 6 hours @25 ml/h, >2 hours @999 ml/h
• battery charging facilities	Automatically charges when pump is connected to AC power
Facilities	
• pumping mechanism	Peristaltic
• administration set	Standard set has anti-reflux valve, set with anti free-flow valve can be purchased
• accessories	Drop sensor, Asena DS docking station.
• flow rate range	1 to 999 ml/h in standard mode, 1.0 ml/h to 99.9 ml/h in micro mode
• flow rate increments	Standard mode: 1 ml/h initially, increasing to 10 ml/h and 100 ml/h increments if pressure sustained on chevron; Micro mode: 0.1 ml/h initially, increasing to 1 ml/h and 10 ml/h increments.
• delivery options	rate and volume, volume over time, primary/secondary infusions, bolus, rate titration - requires key press to confirm, micro mode - allows setting of rate in resolution of 0.1 ml/h increments, KVO, VTBI, VI
• volume infused indicator	1 to 9999 ml in standard mode, 0.1 to 999 ml in micro mode.
• KVO rate	Configurable (OFF, 1.0 to 5.0 ml/h)
• Bolus rate and volume	Rate 1-999 ml/h, volume 0.1-99 ml
• claimed accuracy	+/- 10% over one hour at 1-999 ml/h
• occlusion detection system	Lo (250 mmHg), Nor(mal) (350 mmHg, Hi (500 mmHg)
• alarms and alerts	Alarms: Air in line, upstream occlusion, battery depleted, door open, system fault, flow error (if flow sensor in use), flow sensor connection error, downstream occlusion, misloaded or otherwise incorrect administration set. Warnings: bolus being administered, end of infusion, pump priming, low battery, pump on hold, pump unattended, automatic set checking.
• air in line detection	Configurable single bubble of 50, 100, 250, 500 µl; cumulative > 500 µl over 15 minutes
• drug libraries	No
• type of display	7-Segment display and LEDs

Product Data (continued)	
• type of infusion fluids	Fluid to be infused is dependent on the user selecting the appropiate giving set, choosing compatible material, set make-up (y-sites, filters, and back check valves)
Nurse call facility	Yes
Computer interface	Yes, RS232C
Mounting method	Pole (horizontal or vertical) and in docking station
Protection against fluid ingress	IPX-1
Electrical safety classification	Class 1, CF IEC 601-1
Model identification	
• Serial number	250412127
• Software version number	V5R1F
Product Support	
Servicing and training	Address as for manufacturer Clinical Training 0800 9178776 Technical Support & Training 0800 3896972 Fax: 01256 330860 UK-Technical-Support@alarismed.com UK-Customer-Service@alarismed.com for Clinical Training
Provisions for staff training	
• initial in-service training	Yes, provided at no charge. The Alaris Clinical Training team will work with the trust or hospital to devise an appropriate training schedule which addresses all identified user needs and accommodates any ideas or training programs already established. The training programme utilised will incorporate existing Trust policies and Guidelines.
• follow-up in-service training	Provided on demand at no charge
• first line maintenance training	Familiarization training is available on site at no cost. This training is recommended to be requested early upon devices being issued to the user or during the commissioning process.
• full service/maintenance training	Fully Comprehensive training courses are available on site or at manufacturers premises. Cost £950 per course with up to 8 engineers accommodated. Course is externally accredited and certificated.
Warranty	Two year on-site warranty; extended warranty can be purchased at any time from the point of purchase up to six months after the existing warranty; cost £130 per pump/year.
Maintenance provisions	
• recommended service interval	Annually
• contract service/maintenance	Alaris offer many types of on-site maintenance contracts from PPM coverage to fully comprehensive. Please contact Alaris for further information.
• temporary loan equipment	Available at supplier's discretion
Spare parts	
• spares availability	Maximum two days from receipt of order.
• cost of parts and materials	Prices available on request.
Accompanying manuals	
• operations manual and/or technical/service manual	Free of charge with purchase of pump., Additional copies available from the Alaris Webpage, www.alarismed.com

Appendix 1

User assessment questionnaire

Please complete the attached questionnaire without conferring with colleagues. The results should represent your own opinion. All assessors' identities are confidential and are not used in the evaluation report. We may need to contact you to clarify your responses, and have requested some personal details in order to balance the survey population. The results of this survey will be used as the basis of a 'user assessment', forming part of an MHRA device evaluation.Thank you in advance for your assistance.

Assessor information:	**Circle as appropriate**	
Name:		
Gender:	Male	Female
Handedness	Left	Right
Clinical speciality		
Number of months using the pump		
How frequently do you use this pump weekly?		

The questionnaire is divided up into sections covering different infusion processes. All questions require evaluation on a scale of 1 to 5 where:

5 Very good, could not realistically be any better

4 Good but could be improved

3 Adequate

2 Less than adequate but could be worse

1 Extremely poor

There is also space for additional comments. These are often the most valuable source of information from the assessment so please take the time to add any comments that occur to you.

1. Product Training

Was specific training received for this device: Yes/No. If No go to question 2.

	V. good	Good	Adequate	Inadequate	Poor	
1. The specific training for this device was:	5	4	3	2	1	No comment
Additional comments:						

Training was supplied by:	Please tick all that apply
a) manufacturer	
b) tuition by a previously trained colleague	
c) tuition by a Trust-based trainer	
d) other	

2. User Instructions

Were user instructions available to you during use of the device: Yes/No. If No go to question 3.

	V. good	Good	Adequate	Inadequate	Poor	
2a. The overall quality of the user instructions for this device was:	5	4	3	2	1	No comment
Additional comments:						
2b.How would you assess the readability of the manual(s):	5	4	3	2	1	No comment
Additional comments:						
2c. The coverage of the instructions was	5	4	3	2	1	No comment
Additional comments:						
2d. The user instructions on the body of infusion pump were:	5	4	3	2	1	No comment
Additional comments:						

3. Appropriateness of Device

	V. good	Good	Adequate	Inadequate	Poor	
3a. The device's suitability for your application was:	5	4	3	2	1	No comment
Additional comments:						
3b. The battery life was:	5	4	3	2	1	No comment
Additional comments:						
3c. The size of the pump was:	5	4	3	2	1	No comment
Additional comments:						
3d. The weight of the pump was:	5	4	3	2	1	No comment
Additional comments:						
3e. The ease of moving pump when disconnected from patient and stand was:	5	4	3	2	1	No comment
Additional comments:						
3f. The robustness of the pump was:	5	4	3	2	1	No comment
Additional comments:						
3g. The pole clamp was:	5	4	3	2	1	No comment
Additional comments:						

4. Administration Set

	V. good	Good	Adequate	Inadequate	Poor	
4a. The suitability of the supplied administration set was:	5	4	3	2	1	No comment
Additional comments:						

5. Loading the Set

	V. good	Good	Adequate	Inadequate	Poor	
5a. The loading procedure for the set/syringe was:	5	4	3	2	1	No comment
Additional comments:						
5b. The priming procedure for the set/syringe was:	5	4	3	2	1	No comment
Additional comments:						
5c. The ease of setting syringe brand and size was: (syringe pump only)	5	4	3	2	1	No comment
Additional comments:						

6. Setting parameters and Starting Infusion

	V. good	Good	Adequate	Inadequate	Poor	
6a. The ease of setting the rate was:	5	4	3	2	1	No comment
Additional comments:						
6b. The ease of setting the VTBI was:	5	4	3	2	1	No comment
Additional comments:						
6c. The ease of navigating the control panels was:	5	4	3	2	1	No comment
Additional comments:						
6d. The visual displays were:	5	4	3	2	1	No comment
Additional comments:						
6e. The clarity of messages were:	5	4	3	2	1	No comment
Additional comments:						

7. Monitoring the Infusion

	V. good	Good	Adequate	Inadequate	Poor	
7a. The noise level whilst running was:	5	4	3	2	1	No comment
Additional comments:						
7.b. The running indicator clarity was:	5	4	3	2	1	No comment
Additional comments:						
7c. The display of rate/VTBI during an infusion was:	5	4	3	2	1	No comment
Additional comments:						
7d. The alarm messages were:	5	4	3	2	1	No comment
Additional comments:						
7e. The alarm tone was:	5	4	3	2	1	No comment
Additional comments:						
7f. The appropriateness of alarms were:	5	4	3	2	1	No comment
Additional comments:						
7g. The safeguards against tampering were:	5	4	3	2	1	No comment
Additional comments:						

8. Infusion Complete

	V. good	Good	Adequate	Inadequate	Poor	
8a. The ease of cleaning was:	5	4	3	2	1	No comment
Additional comments:						
8b. The ease of charging was:	5	4	3	2	1	No comment
Additional comments:						

9. General Questions

9a. List any features that you would like to see which are not present on this pump:

9b. List any features that are present but which are unsuitable for your application:

9c. Are there any additional comments that you would like to make on your experience of using this pump?

Methodology

Tests are undertaken in accordance with the techniques outlined in BS EN 60601-2-24:1998 with variations where indicated*. A new administration set or syringe is used for each test.

The parameters constancy index, resumption time, pump height bolus, pump height negative bolus are new concepts, and are proposed variations to the Standard IEC 60601-2-24. Algorithms used for their calculation can be provided on request from bime@bath.ac.uk

Disclaimer

For all tests, only one pump and a limited number of disposables is tested. The quoted results are a measure of the performance of this one pump. It cannot be assumed that other devices of the same type will behave identically.

Long term accuracy

*Rates tested: minimum, 1, 5, 25, (125 for volumetric pumps) and maximum. *Test durations are generally 2 hours except the 1 ml/h test (24 hours) and minimum rate test (4 hours). Accuracy is assessed over the last hour for all tests, excepting the 24 hour test where each of the last 18 hours is assessed.

Flow accuracy is monitored over the second and last hours of the manufacturer's recommended maximum life of the administration set. The test is run at 500 ml/h (or maximum if lower) for volumetric pumps. Syringe pumps are run for 48 hours at 1 ml/h. Any change in the measured hourly delivery rate over the lifetime of the set/syringe is noted.

Short term accuracy

Short-term accuracy is characterised using a new parameter known as constancy index. The constancy index provides a guide to the minimum half-life of drugs suited for administration with the pump undergoing evaluation.

Constancy index is measured at 1 ml/h for all pumps during a test run of 24 hours duration. A discussion of this new concept is included in Evaluation report 02110 and can be provided on request by BIME.

Flow accuracy under back-pressure

The pump is set up to infuse for a continuous period of 8 hours comprising 2 hours at ambient back-pressure, followed by 3 hours at -100 mmHg and then 3 hours at

+100 mmHg. At the points when the back-pressure is changed, the pump is not stopped and settings are not altered. The long-term accuracy is calculated for each period of the test. The parameters resumption time, pump height bolus and pump height negative bolus are calculated.

Volume to be infused (VTBI) accuracy

The infusion pump is set to the required rate, with the VTBI facility set such that the infusion will last one hour. Errors for both time, and volume delivered are measured. Tests are performed at 1 ml/h and 25 ml/h for all pump types.

Changes in fluid container height

(volumetric pumps only)

The pump is set up to infuse with the drip chamber of the fluid container positioned at a nominal 30 cm above the top of the pump. After a control period of 2 hours, the fluid container is elevated to the maximum height obtainable above the pumping mechanism for 1.5 hours, and then lowered to the minimum height while still remaining operable (or 0.5 m if less) for a final 1.5 hours. Accuracy is measured and compared over each of these three periods.The pump is not stopped and settings are not altered when moving the fluid container. Rate: 125 ml/h.

Battery performance

After appropriate discharge and recharge cycling, the delivery accuracy is measured at 1 ml/h for syringe pumps and 125 ml/h for volumetric pumps, with mains supply disconnected, until the infusion pump stops due to battery depletion. Long term accuracy over the second and the final hour of the test are calculated to assess any performance impairment due to battery depletion. The duration of operation is noted. The equipment is also tested for accurate delivery upon re-application of mains power. It is noted whether infusion settings are retained and whether the pump shuts down safely.

Bolus volume accuracy

Where the equipment is intended to administer a discrete bolus volume to the patient, the accuracy of this feature is measured. To test lockout facilities on PCA pumps, a 5 minute lockout time is set. A bolus is demanded and then subsequent demands are made periodically to establish when the next bolus is permitted.

0.1 ml, 1.0 ml and 5.0 ml target bolus volumes are tested for all pump types.

Body temperature test

A 2 hour flow test at 1 ml/h is performed with the pump and delivery fluid contained within an incubator at a temperature of 37 °C.

Patient-side occlusion alarm response

Time to alarm and bolus on release of occlusion are measured at 1, 5, and 25 ml/h for syringe pumps, (1, 5, and 125 (or maximum if less) ml/h for volumetric pumps). *Pressure at alarm is not measured during these tests (Pressure per se is not considered a hazard to the patient.) The 1 ml/h tests using the main recommended disposable are repeated 5 times each for three nominally identical disposables.

For PCA pumps, the number of attempted bolus deliveries before alarm is recorded, and the bolus delivered on release of the occlusion.

Back-off

Pumps commonly have a facility to run the pumping mechanism backwards on occurrence of an occlusion alarm. Line pressure is recorded at one second intervals for an occlusion response at 1 ml/h and 5 ml/h. A graphical display of the pressure variation over time is produced to indicate the operation of a back-off system. Any anomalous behaviour, such as a pressure falling below atmospheric, is noted.

Pressure at alarm is also recorded for one of these tests as a rough check of the manufacturer’s claims and correct functionality.

Fluid side occlusion response

The response of the pump to an upstream occlusion is observed and recorded whether or not an alarm system is provided. The response is assessed for patient safety (as examples, tubing rupture or air entry represent significant hazards). The time to alarm is recorded 3 times at each test flow rate. Tests are performed at 1 ml/h and maximum rate on volumetric pumps only.

Air-in-line detection

Significant uncertainties exist in the testing of this feature. The air detector sensitivity is set to 50 µl or minimum if greater. Three consecutive test volumes of air are introduced immediately up-stream of the infusion pump. The infusion pump should alarm for each test volume.Tests are performed at 125 (or maximum if less) ml/h. If the test is failed, a larger volume of air is injected until a pass is obtained. The test is for functionality rather than sensitivity.

Syringe recognition system

The syringe pump is tested systematically to find the worst case of incorrect recognition of syringe size and a flow delivery accuracy test is run at 5 ml/h to estimate the worst case error that this user error can cause. All available syringes recommended for use with the pump are also tested to assess the response to misloading of the barrel, plunger or ears.

Line tugging test

The delivery line is tugged sharply in a variety of directions and potential hazards assessed.

Testing of device ergonomics

Most Adverse Incidents are eventually denoted as user error. Good design can contribute to minimising user error. Work has been initiated to develop a formal ergonomic testing procedure for application to all devices. At present, User instructions are assessed for clarity and readability, conciseness, indexing. Procedures for using the device are systematically worked through on the bench after other testing is completed. Any hazardous potential misuse is noted.

For all available alarms, the reliability, readability of text displayed, the alarm tone quality, the positioning of alarm lights and methods of silencing alarms are tested as part of the ergonomic assessment of the device.

Manufacturer's comments

The report compiled by BIME is a reasonable assessment of the Asena® GW Volumetric pump. We have, at the time this report was finalised, yet to complete our investigation into the cause of the ruptured administration set reported during this assessment; this failure mode has not been previously reported to us or observed during testing of the device and associated disposable.